REMARKS

Claims 1 - 17 are pending in the application. Claims 1 - 11 and 13 are rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 5,743,251, to Howell et al., in view of U.S. Patent No. 5,747,001, to Wiedmann et al.

Claims 1 - 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 6,776,978; 6,716,417; 6,797,259; 6,740,309; 6,743,415; 6,737,042; 6,814,955; 6,805,584; 6,716,415; 6,803,031; 6,759,029; 6,737,043; 6,740,308; 6,740,307; 6,716,416; 6,783,753; 6,780,400; 6,780,399; 6,805,853; and 6,814,954.

Claims 1 - 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending U.S. Application Nos. 10/815,527; 10/816,492; 10/786,220; 10/766,574; 10/813,721; 10/767,115; 10/816,567; 10/766,279; 10/766,641; 10/814,998; 10/718,982; 10/769,157; 10/769,197; 10/769,051; 10/768,205; 10/766,647; 10/792,013; 10/792,012; 10/766,634; 10/766,566; 10/768,293; 10/791,915; and 10/775,586.

Claims 8 and 9, which stated, respectively, that the mass median aerodynamic diameter of the condensation aerosol is between 10 nm and 900 nm (0.9 μm), and between 10 nm and 500 nm (0.5 μm), have been cancelled, because Claim 1 (from which Claims 8 and 9 depend) recites that the mass median aerodynamic diameter is less than 0.1 μm, and the upper limits of 900 nm and 500 nm in Claims 8 and 9 are greater than 0.1 μm.

Claims 1 - 3, 5, and 6 have been amended. Claims 8 and 9 have been cancelled. New Claims 18 - 39 have been added. Applicant respectfully request reconsideration of the application, withdrawal of all rejections, and allowance of the application in view of the amendments and remarks below.

The Amendments to the Claims

The amendments to the claims are believed to place the application in condition for allowance. Without prejudice to the applicants' rights to present claims of equal scope in a timely filed continuing application, to expedite prosecution and issuance of the application, the applicants have amended claims 1-3, 5 and 6.

The amendments to the claims do not introduce new matter. Applicants respectfully submit that the amendments to the claims put the case in condition for allowance. The Examiner is respectfully requested to enter the amendments to the claims and allow all claims.

Claim Rejections Under 35 USC § 103

Claims 1 - 11 and 13 are rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 5,743,251, to Howell et al., in view of U.S. Patent No. 5,747,001, to Wiedmann et al.

In the "Response to Arguments" section on page 4 of the present Office Action, the Examiner states that "Applicant's arguments with respect to claims 1-17 have been fully considered but they are not persuasive". The Examiner goes on to state that "Applicant argues that Howell et al do not 'disclose or suggest depositing a drug on a substrate, as required by Claim 1 of the present application.' This is not persuasive because Howell et al teaches placing the drug in a tube, and it is considered that a 'tube' reads on 'a substrate'. Instant claims do not specify any form for the drug, thus Howell's 'liquid' also reads on the instant 'drug'."

Applicants stand behind the arguments made in their Amendment submitted on April 20, 2006. However, in the interest of obtaining timely allowance of the subject application, step a) of independent Claim 1 has been amended to recite "depositing a drug composition on a substrate, wherein said deposited drug composition has a surface over which a gas can flow".

According to the method disclosed in Howell et al., a material in liquid form is supplied to a tube having an open end. The liquid material filling the tube is heated such that the liquid material volatilizes and expands out of the open end of the tube (Col. 2, lines 18 - 25). Col. 3, lines 38 - 43, of Howell et al. states as follows: "The tube 23 may be closed at a second end 31 and material in liquid form may be introduced into the tube 23 through the open end 25 when it is desired to form an aerosol. Thus, when the liquid material is heated by the heater 27, the volatilized material is only able to expand by exiting the tube 23 through the open end 25." The fact that the only avenue for expansion of the volatilized material is through the open end of the tube indicates that the liquid material completely fills the inside of the tube during operation of the device. As the liquid material completely fills the inside of the tube, the liquid material taught by Howell et al. clearly does not have a "surface over which a gas can flow", as described by applicants in their specification and as claimed in applicants' amended Claim 1.

Applicants submit that the amendment to Claim 1 clearly distinguishes applicants' claimed invention from the "liquid-filled tube" disclosed by Howell et al. As stated above, the amendment to Claim 1 was made solely for the purpose of advancing the subject application to allowance, and should not be construed as agreement with or acquiescence to the Examiner's rejection of Claims 1 - 11 and 13 over Howell et al.

Wiedmann et al. pertains to an aerosol comprising droplets of an aqueous dispersion of nanoparticles, where the nanoparticles comprise insoluble beclomethazone particles having a surface modifier on the surface thereof. [Abstract] Although Wiedmann et al. states "In some embodiments, an effective average particle size of less than about 100 nm has been achieved" (Col. 10, lines 31 - 32), in the "Results" section at Col. 12, lines 30 - 33, Wiedmann et al. states: "Nanoparticles of beclomethasone diproprionate in 2.5% polyvinyl alcohol had a particle size distribution of 0.26 ± 0.13 μm. This size remained constant throughout the course of the study . . ." This means that the smallest particle size actually obtained by Wiedmann et al. was 0.13 μm (130 nm). By contrast, applicants disclose the actual preparation of aerosolized drug particles having MMADs of 80 nm (page 30, paragraph [0171] of applicants' specification); 71, 72 - 78, and 77 - 78 nm (page 32, Table 2); 65 nm (page 34, Table 4); and 92 nm (page 35, Table 5).

Even if one were to combine the teachings of Wiedmann et al. with those of Howell et al., one skilled in the art would not be led to make applicants' presently claimed invention.

Applicants submit that, whether taken alone or in combination, neither Howell et al. nor Wiedmann et al. teaches or even suggests applicants' presently claimed invention. In light of the above arguments and the amendment to independent Claim 1, applicants respectfully request withdrawal of the rejection of Claims 1 - 11 and 13 under 35 USC § 103(a), over Howell et al., in view of Wiedmann et al.

New Claims

New Claims 18 - 39 have been added. New Claim 18, which depends from Claim 1, states that "depositing of said drug composition on said substrate is accomplished by mixing said drug composition with an organic solvent to dissolve said drug composition, followed by evaporation of said solvent". Claim 18 is supported in paragraph [0092] on page 13, and in paragraph [0195] on page 36, of applicants' originally filed specification. In particular, paragraph [0195] states as follows: "Deposition of the compound onto the screen was

accomplished by mixing the compound with an organic solvent until the compound dissolved. The resulting solution was then applied to the fine stainless steel screen **902** and the solvent was allowed to evaporate."

New Claims 19 - 21 depend from Claim 6, which states that the drug composition is deposited onto the substrate as a thin film. Claims 19 - 21 recite various thickness ranges for the thin film. The claimed thickness ranges are supported in paragraph [0117] on page 20 of applicants' originally filed specification.

New independent Claim 22 is similar to Claim 1, with the exception that step a) requires "coating a drug composition onto a substrate". Claim 22 is supported in paragraphs [0117] and [0118] on page 20 of applicants' specification, for example. Claims 23 - 39 depend from Claim 22.

Applicants submit that completely filling a tube with a liquid (as disclosed by Howell et al.) is different from coating a drug composition onto a substrate. As such, applicants contend that new Claims 23 - 39 are clearly distinguishable over the teachings of Howell et al.

Applicants contend that the new claims and the amendments to the claims set forth above are fully supported by applicants' originally filed specification and drawings, and that no new matter has been added to the application by the new claims or claim amendments.

Double Patenting Rejections

Claims 1 - 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 6,776,978; 6,716,417; 6,797,259; 6,740,309; 6,743,415; 6,737,042; 6,814,955; 6,805,854*; 6,716,415; 6,803,031; 6,759,029; 6,737,043; 6,740,308; 6,740,307; 6,716,416; 6,783,753; 6,780,400; 6,780,399; 6,805,853; and 6,814,954.

* U.S. Patent No. 6,805,584 corrected to U.S. Patent No. 6,805,854, as discussed with the Examiner.

Claims 1 - 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending U.S. Application Nos. 10/815,527; 10/816,492; 10/786,220; 10/766,574; 10/813,721; 10/767,115; 10/816,567; 10/766,279; 10/766,149**; 10/814,998; 10/718,982; 10/769,157; 10/769,197; 10/769,051; 10/768,205; 10/766,647; 10/792,013; 10/792,012; 10/766,634; 10/766,566; 10/768,293; 10/791,915; and 10/775,586.

When the present claims are determined to be patentable, applicants will submit Terminal Disclaimers with regard to the above-referenced issued U.S. patents and copending U.S. applications. Applicants believe that this will address the Examiner's concerns and respectfully request reconsideration of the application, withdrawal of all rejections, and allowance of the application in view of these actions and remarks.

Closing Remarks

Applicants appreciate the Examiner's careful and thorough review of the application and submit that the Examiner's concerns have been addressed by the amendments and remarks above. Applicants accordingly request that the Examiner withdraw all rejections and allow the application. In the event that the Examiner believes that a telephonic discussion would expedite allowance or help to resolve outstanding issues in the prosecution of the application, the Examiner is invited to call the undersigned at the telephone number set forth below.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

** U.S. Application Serial No. 10/766,641 corrected to 10/766,149, as discussed with the Examiner.

Applicants respectfully request reconsideration of the application, withdrawal of all rejections, and allowance of the application in view of the amendments and remarks set forth above.

Respectfully submitted,

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